UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NORTHEASTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	No. _____
v.	)	
	)	
OAKLEY PHARMACY, INC., d/b/a DALE HOLLOW PHARMACY; XPRESS PHARMACY OF CLAY COUNTY, LLC; THOMAS WEIR; MICHAEL GRIFFITH; JOHN POLSTON, and LARRY LARKIN,	)	JURY DEMAND
	)	**UNDER SEAL**
Defendants.	)	

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF AND CIVIL MONETARY PENALTIES UNDER THE CONTROLLED SUBSTANCES ACT, AND FOR FALSE CLAIMS ACT RELIEF

1. The United States of America brings this action against Oakley Pharmacy, Inc., doing business as Dale Hollow Pharmacy; Xpress Pharmacy of Clay County, LLC; Thomas Weir; John Polston; Michael Griffith, and Larry Larkin seeking injunctive relief and civil monetary penalties for Defendants' violations of the Controlled Substances Act, 21 U.S.C. § 801, *et seq.* (the "CSA") and its implementing regulations, 21 C.F.R. § 1301, *et seq.* Those violations include: (a) knowingly dispensing controlled substances without a valid prescription in violation of 21 U.S.C. § 842(a)(1); and (2) knowingly and intentionally distributing and dispensing controlled substances outside the usual course of the professional practice of pharmacy, in violation of 21 U.S.C. § 841(a). The United States also seeks to recover monies that Defendants caused the Medicare program to pay for controlled substances that were not used for a medically accepted indication and lacked a legitimate medical purpose in violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq*.

INTRODUCTION

2. The nation is experiencing a national public health emergency involving opioid abuse. The dispensing and distribution of controlled substances, including prescription opioid painkillers, without a legitimate medical purpose and outside the usual course of professional practice exacerbate this crisis. This crisis impacts Tennessee individuals and families as well as the Medicare program when its funds are used to pay for improperly dispensed controlled substances.

3. Defendants have both fueled and profited from this epidemic by repeatedly dispensing opioids and other controlled substances prone to abuse without a legitimate medical purpose and outside the usual course of professional medical practice. Within the last 26 months, Defendants' unlawful dispensing has been tied to the deaths of several people. In addition to these deaths, at least five customers of Xpress and seven Dale Hollow customers – all of whom were Medicare beneficiaries – have been treated for drug overdoses at hospitals, and some of them were admitted for overdoses more than once.

4. In addition to seeking civil monetary penalties for Defendants' past violations of the CSA, the United States seeks an order preliminarily and permanently enjoining Defendants and those acting in concert and participation with them from continuing to unlawfully dispense controlled substances in order to protect the public from any further harm.

5. The United States also seeks to recover treble damages and civil penalties arising from Defendants' violations of the FCA.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter and all parties to this action pursuant to 21 U.S.C. §§ 842(c)(1)(A) and 882(a), 28 U.S.C. §§ 1331, 1345, 1355, and 1367(a), and

31 U.S.C. §§ 3730(a) and 3732(b).

7. Venue is proper in the Middle District of Tennessee under 21 U.S.C. § 843(f)(2), 28 U.S.C. §§ 1391(b) and 1395(a), and 31 U.S.C. § 3730(a) and 3732(b), because the Defendants are located, reside, do business, or committed the acts at issue in this district.

THE PARTIES

8. Plaintiff United States of America brings this action on behalf of the Department of Justice, as delegated to the Drug Enforcement Administration ("DEA"), which regulates the distribution of controlled substances under the authority of the CSA, and on behalf of the Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS"), which administer the Medicare and Medicaid programs.

9. Defendant Oakley Pharmacy, Inc., does business as a retail pharmacy known alternatively as Dale Hollow Pharmacy and Dale Hollow Health Mart Pharmacy (hereinafter "Dale Hollow") and is a corporation formed and registered under the laws of the State of Tennessee which does business as a retail pharmacy, with its principal place of business in Celina, Clay County, Tennessee.

10. Defendant Xpress Pharmacy of Clay County, LLC (hereinafter "Xpress") is a limited liability company formed and registered under the laws of the State of Tennessee which does business as a retail pharmacy, with its principal place of business in Celina, Clay County, Tennessee.

11. Defendant Thomas Weir is the majority owner (51%) of both Dale Hollow and Xpress and serves as Dale Hollow's Chief Executive Officer and Xpress' majority member. Weir resides in Celina in Clay County, Tennessee. At all times relevant to this Complaint, Weir operated, was a principal of, and exercised control over Dale Hollow and Xpress, and was acting within the

full course, scope, and authority of Weir's positions with Dale Hollow and Xpress.

12. Defendant John Polston is the pharmacist-in-charge of Dale Hollow and is licensed to practice pharmacy by the States of Tennessee and Kentucky. Under Tennessee law, as pharmacist-in-charge, Polston is "the supervisory pharmacist who has the authority and responsibility for compliance with laws and rules pertaining to the practice of pharmacy at the practice site of the pharmacist-in-charge." Tenn. Code Ann. § 63-10-204(31). At all times relevant to this Complaint, Polston was acting within the scope of his employment and duties as an agent, servant, and employee of, and in furtherance of the business interests of, Dale Hollow and Weir. Polston resides in Tompkinsville, Kentucky.

13. Defendant Michael Griffith is the pharmacist-in-charge of Xpress and is licensed to practice pharmacy by the State of Tennessee. Under Tennessee law, as pharmacist-in-charge, Griffith is "the supervisory pharmacist who has the authority and responsibility for compliance with laws and rules pertaining to the practice of pharmacy at the practice site of the pharmacist-in-charge." *Id.* At all times relevant to this Complaint, Griffith was acting with the scope of his employment and duties as an agent, servant, and employee of, and in furtherance of the business interests of, Xpress and Weir. He resides in Mount Juliet, Tennessee.

14. Defendant Larry Larkin works as a part-time pharmacist at both of the pharmacies owned by Weir, Dale Hollow and Xpress. Larkin is licensed to practice pharmacy by the State of Tennessee. At all times relevant to this Complaint, Larkin was acting within the scope of this employment and duties as an agent, servant, and employee of, and in furtherance of the business interests of Weir, Dale Hollow, and Xpress. He resides in Knoxville, Tennessee.

GENERAL ALLEGATIONS

THE NATIONWIDE OPIOID CRISIS

15. On October 26, 2017, at the direction of the President of the United States, the HHS Secretary declared the opioid epidemic a national public health emergency under federal law. This declaration recognizes the immense human and financial toll the opioid crisis has inflicted on the country. The statistics show the gravity of the situation:

a. Nearly 350,000 Americans died from an opioid-related drug overdose between 1999 and 2016.

b. In 2016, 116 Americans died every day from an opioid-related overdose. And 11.5 million Americans misused prescription opioids; 2.1 million did so for the first time.

c. Between July 2016 and September 2017, the number of emergency room visits for opioid-related overdoses jumped nearly 30%.

d. Just a few weeks ago, the congressionally-chartered National Safety Council revealed that, for the first time in U.S. history, a person is more likely to die from an accidental opioid overdose than from a motor vehicle crash. The analysis showed that the odds of dying from opioid overdose are also higher than from falls, drowning, gun assault, or choking.[1]

16. Tennessee has not been spared the effects of this crisis. According to HHS' Centers

[1] NAT'L SAFETY COUNCIL, INJURY FACTS, https://injuryfacts.nsc.org/all-injuries/preventable-death-overview/odds-of-dying/ (last visited Jan. 26, 2019); *see also* Press Release, Nat'l Safety Council, *For the First Time, We're More Likely to Die from Accidental Opioid Overdose than Motor Vehicle Crash* (Jan. 14, 2019) (available at https://www.nsc.org/in-the-newsroom/for-the-first-time-were-more-likely-to-die-from-accidental-opioid-overdose-than-motor-vehicle-crash).

for Disease Control and Prevention ("CDC"), retail opioid prescriptions were dispensed in 2017 at a national rate of 58.7 prescriptions per 100 persons.[2] The frequency across Tennessee is nearly double the national rate (94.4).[3] And in Clay County, where Defendants operate two of the four pharmacies in a county that has less than 8,000 residents, that rate is a stunning 191.3.[4] That means opioids were dispensed in Clay County at a rate sufficient for every man, woman, and child in the county to get their own prescription—*twice*. In fact, only four counties in the entire United States dispense more opioid prescriptions per capita than the pharmacies of Clay County.

17. According to DEA data, between 2015 and 2018, Dale Hollow alone ordered enough morphine milligram equivalents[5] ("MME") of opioids from pharmaceutical distributors to provide the equivalent of almost one-and-a-half maximum-strength Vicodin (hydrocodone/acetaminophen) pills every day to each man, woman, and child in Clay County.

18. Meanwhile, three doors down the street from Dale Hollow, Xpress Pharmacy – with the same owner – was on its own ordering enough opioids during the same period to provide the same residents the equivalent of an additional half a tablet of maximum strength Percocet (oxycodone/acetaminophen) every day, according to the same DEA data.

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[2] U.S. Ctrs. for Disease Control & Prevention, *U.S. Opioid Prescribing Rate Maps*, https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html (last visited Feb. 7, 2019).

[3] U.S. Ctrs. for Disease Control & Prevention, *U.S. State Prescribing Rates, 2017,* https://www.cdc.gov/drugoverdose/maps/rxstate2017.html (last visited Feb. 7, 2019).

[4] U.S. Ctrs. for Disease Control & Prevention, *U.S. County Prescribing Rates, 2017,* https://www.cdc.gov/drugoverdose/maps/rxcounty2017.html (last visited Feb. 7, 2019).

[5] Morphine milligram equivalents (sometimes called "morphine equivalent dose") is a standard value assigned to opioids to represent their relative potency that uses an equivalency factor to calculate a dose of morphine that is equivalent to the prescribed opioid. As a result, the strength of every opioid can be converted to the equivalent of one medication – morphine – thereby enabling an apples-to-apples comparison of opioid potency using morphine as the standard. For example, a 10 mg dose of oxymorphone is equivalent in strength and risk to approximately 30 mg of morphine. Thus, a 10 mg dose of oxymorphone can be expressed as 30 MMEs.

19. There are roughly 68,000 community pharmacies in the United States. Only ***three*** of those 68,000 pharmacies purchased more opioid doses per capita than Dale Hallow over the last three years. Xpress just misses being in the top-ten in the nation, ranking at number eleven, using the same measure.

20. Dale Hollow purchases more buprenorphine – an opioid chiefly used to prevent withdrawal symptoms in those addicted to other opioids – than all but two pharmacies in the entire state. Another Tennessee top-20 purchaser of buprenorphine is situated a mere 100 yards away: Xpress Pharmacy.

21. Because buprenorphine is itself an opioid used to treat those dependent on opioids, like methadone, it is highly susceptible to abuse. To help safeguard against such abuse, in addition to pure buprenorphine (brand name, Subutex), buprenorphine is also available in a formulation that contains naloxone as an anti-abuse component (brand name, Suboxone).[6] Recognizing the high potential for buprenorphine abuse, Tennessee law requires that the monotherapy formulation (Subutex) may only be prescribed for a patient who is "pregnant; a nursing mother; or has a documented history of an adverse reaction or hypersensitivity to naloxone." Tenn. Code Ann. § 53-11-311(b)(1).

22. Patients requiring monotherapy rather than the anti-abuse formulation are extremely uncommon. Only around 4% of American women are pregnant at any given time and only about half of them are nursing six months after birth. Moreover, the Tennessee Department

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[6] Naloxone (brand name, Narcan) is an opioid antagonist, or "blocker." The naloxone in the combination formulation (Suboxone) is only absorbed and activated in the body if injected instead of being dissolved in the mouth as prescribed. If injected by someone dependent on opioids, the antagonistic effect of the Naloxone predominates, causing unpleasant withdrawal symptoms while blocking the opioid-effects of the buprenorphine component, thus discouraging misuse and abuse of the combination product.

of Health's guidelines for buprenorphine treatment specifically warn:

> An adverse reaction or hypersensitivity to a buprenorphine with naloxone product is rare. **If a provider is prescribing buprenorphine without naloxone**, due to adverse reaction or hypersensitivity, **to more than 5% of their patients receiving a buprenorphine-containing product, the provider should reevaluate his/her practice habits** and may be subject to review by the Boards of Medical Examiners or Osteopathic Examination. All patients receiving buprenorphine without naloxone shall have proper justification documented in the patient's medical record.[7]

Accordingly, one could reasonably deduce that no more than about 10% of buprenorphine prescriptions filled at pharmacies in Tennessee would be for the monotherapy formulation.

23. In fact, approximately 90% of buprenorphine prescriptions filled at Dale Hollow and 83% of those filled at Xpress are for the monotherapy formulation; that is, pure buprenorphine without the anti-abuse safeguard.

24. The harm is real. In 2017, there were 644 deaths in Tennessee from prescription opioid overdoses. And the majority of these individuals (58%) filled a prescription for a controlled substance within 60 days of their death.[8]

25. In March 2016, the CDC, in order to reduce opioid addictions, overdoses, and deaths, published specific recommendations for clinicians who prescribe opioids outside of cancer treatment, palliative care, and end-of-life care.[9] The CDC recommendations are based on

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[7] TENN. DEP'T OF MENTAL HEALTH & SUBSTANCE ABUSE SERVS. & TENN. DEP'T OF HEALTH, TENNESSEE NONRESIDENTIAL BUPRENORPHINE TREATMENT GUIDELINES 13 (2018) (available at https://www.tn.gov/content/dam/tn/mentalhealth/documents/ FINAL%20Buprenor-phine%20Treatment%20Guidelines-Summer%202018.pdf)

[8] Tenn. Dep't of Health, *2017 Tennessee Drug Overdose Deaths* 5–7 (Sep. 5, 2018), https://www.tn.gov/content/dam/tn/health/documents/pdo/Fatal%20Drug%20Overdose%20in%20TN%20Report_2017.pdf.

[9] *See generally* Deborah Dowell, M.D. et al., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, 65 MORBIDITY & MORTALITY WKLY. REP. 1 (2016) [hereinafter, *CDC Guideline*].

"[s]cientific research [that] has identified high-risk prescribing practices that have contributed to the overdose epidemic (*e.g.*, high-dose prescribing, overlapping opioid and benzodiazepine prescriptions, and extended-release/long-acting opioids for acute pain)."[10]

26. By dispensing controlled substances without a legitimate medical purpose and outside the usual course of professional practice, Defendants unlawfully perpetuate this serious public health crisis.

THE APPLICABLE STATUTES

THE CONTROLLED SUBSTANCES ACT

27. The CSA and its implementing regulations govern the manufacture, distribution, and dispensation of controlled substances in the United States. From the outset, Congress recognized the importance of preventing the diversion of drugs from legitimate to illegitimate uses. The CSA accordingly establishes a closed regulatory system under which it is unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. *See* 21 U.S.C. § 841(a).

28. The CSA categorizes controlled substances in five schedules.

29. Schedule II contains drugs with "a high potential for abuse" that "may lead to severe psychological or physical dependence" but nonetheless have "a currently accepted medical use in treatment." 21 U.S.C. § 812(b)(2).

30. Schedule III contains drugs in which, although the abuse potential is less than a Schedule II drug, such abuse may lead to moderate "physical dependence or high psychological dependence." Schedule III drugs also have "a currently accepted medical use." 21 U.S.C. § 812(b)(3).

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[10] *Id.* at 3.

31. Schedule IV contains drugs that, although having a lower abuse potential than Schedule III drugs, still may lead to a physical or psychological dependence when abused. 21 U.S.C. § 812(b)(4).

32. Schedule V contains drugs that, although having a lower abuse potential than Schedule IV drugs, still may lead to a physical or psychological dependence when abused. 21 U.S.C. § 812(b)(5).

33. The CSA makes it "unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance" except as specifically authorized by the CSA. 21 U.S.C. § 841(a)(1).

34. Accordingly, the CSA requires those who manufacture, distribute, or dispense controlled substances to obtain a registration from the DEA. 21 U.S.C. § 822(a). A registrant is only permitted to dispense or distribute controlled substances "to the extent authorized by their registration and in conformity with the [CSA]." 21 U.S.C. § 822(b).

35. At all times relevant to this Complaint, Dale Hollow was registered as a retail pharmacy with DEA in Schedule II–V controlled substances under registration number FD2546197.

36. At all times relevant to this Complaint, Xpress was registered as a retail pharmacy with DEA in Schedule II–V controlled substances under registration number FC2576796.

37. Those DEA registrations authorize Dale Hollow and Xpress to "dispense" controlled substances, which "means to deliver a controlled substance to an ultimate user … by, or pursuant to the lawful order of, a practitioner." 21 U.S.C. §§ 823(f), 802(10).

38. Agents and employees of a registered manufacturer, distributor, or dispenser of controlled substances, such as a pharmacist employed by a registered pharmacy, are not required

to register with DEA, "if such agent or employee is acting in the usual course of his business or employment." 21 U.S.C. § 822(c)(1).

39. Under the CSA, the lawful dispensing of controlled substances is governed by 28 U.S.C. § 829 and more specifically in Part 1306 of the CSA's implementing regulations. *See generally* 21 C.F.R. pt. 1306.

40. Unless dispensed directly by a non-pharmacist practitioner, no Schedule II controlled substance may be dispensed without the written prescription of a practitioner, such as a physician, except in an emergency. 21 U.S.C. § 829(a). Similarly, unless directly dispensed, no Schedule III or IV controlled substance may be dispensed without a written or oral prescription from a practitioner. 21 U.S.C. § 829(b).

41. Such a prescription for a controlled substance may only be issued by an individual who is (a) "authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession" and (b) registered with the DEA. 21 U.S.C. § 822; 21 C.F.R. § 1306.03.

42. A prescription, whether written or oral, is legally valid under the CSA **only** if it is issued for "a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). Moreover, "[a]n order purporting to be a prescription issued not in the usual course of professional treatment … is not a prescription within the meaning and intent of [21 U.S.C. § 829] and **the person knowingly filling such a purported prescription**, as well as the person issuing it, **shall be subject to the penalties** provided for violations of the provisions of law relating to controlled substances." *Id.* (emphasis added).

43. As a result, the "responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.* Thus, a pharmacist may not fill a controlled

substance prescription unless it has been issued for a legitimate medical purpose.

44. Moreover, "[a] prescription for a controlled substance may **only** be filled by a pharmacist, **acting in the usual course of his professional practice** and either registered individually, or employed in a registered pharmacy …" 21 C.F.R. § 1306.06 (emphasis added).

45. Pharmacists are therefore permitted to dispense a controlled substance in any given instance if, *but only if*, such dispensation would be in accordance with a generally accepted, objective standard of practice, *i.e.*, "the usual course of his professional practice" of pharmacy. *Id.*

46. Consequently, a pharmacist is required to refuse to fill a prescription if he or she knows or has reason to know that the prescription was not written for a legitimate medical purpose. *See* 21 C.F.R. §§ 1306.04, 1306.06.

47. This requires a pharmacist to use sound professional judgment in determining the legitimacy of a controlled substance prescription, which includes paying attention to the number of prescriptions issued, the number of dosage units prescribed, the doctor writing the prescriptions, and whether the drugs prescribed have a high rate of abuse. The pharmacist has a legal duty to recognize "red flags" or warning signs that raise (or should raise) a reasonable suspicion that a prescription for a controlled substance is not legitimate. The existence of such indicia obligates the pharmacist to conduct a sufficient investigation to determine that the prescription is actually legitimate before dispensing.

THE FALSE CLAIMS ACT

48. The FCA provides, in pertinent part, that a person who:

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . . is liable to the United States Government [for statutory damages and such penalties as are allowed by law].

31 U.S.C. § 3729(a)(1)(A)-(B) (2010).

49. The FCA further provides:

> the terms knowing and knowingly –
> a) mean that a person, with respect to information –
> (i) has actual knowledge of the information;
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
> (iii) acts in reckless disregard of the truth or falsity of the information; and
> b) require no proof of specific intent to defraud[.]

31 U.S.C. § 3729(b)(1).

50. The FCA provides that a person is liable to the United States Government for three times the amount of damages that the Government sustains because of the act of that person, plus a civil penalty of $5,500 to $11,000 per violation for violations that occurred before November 2, 2015 and, for violations that occurred after that date, a civil penalty of between $11,181 and $22,363. 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.5.

THE MEDICARE PROGRAM

51. **Medicare.** Congress established the Medicare Program in 1965 to provide health insurance coverage for people age 65 or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 426, 426a.

52. The Medicare program consists of four parts: A, B, C, and D. Defendants submitted, or caused to be submitted, claims under Medicare Part D.

53. **Medicare Part D Program**. In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"), Pub. L. 108-173, 117 Stat. 2066, which established a voluntary prescription drug benefit program for Medicare enrollees known as Medicare Part D. An individual is eligible to enroll in Part D if the individual lives in the service area of a Part D plan and is entitled to Medicare benefits under Part A or enrolled under Part B.

42 U.S.C. § 1395w-101(a)(3)(A); 42 C.F.R. § 423.30(a).

54. Part D coverage is not provided within the traditional Medicare program. Medicare Part D is based on a private market model. Medicare contracts with private entities known as Part D Plan "Sponsors" to administer prescription drug plans.

55. Part D benefits are delivered by a Part D Plan Sponsor, which is either a prescription drug plan, a Medicare Advantage organization that offers a Medicare Advantage prescription drug plan (MA-PD plan), a Program of All-inclusive Care for the Elderly (PACE) organization offering a PACE plan including qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage. 42 C.F.R. § 423.4.

- **Part D Plan Sponsors Submit Prescription Drug Events for Drugs Covered under Medicare Part D**

56. When a pharmacy dispenses a drug to a Medicare beneficiary, it submits an electronic claim to the beneficiary's Part D plan and receives reimbursement from the Part D Plan Sponsor for the costs not paid by the beneficiary.

57. The Part D Plan Sponsor then notifies CMS that a drug has been purchased and dispensed through a document called a Prescription Drug Event ("PDE") record, which includes data elements about the drug dispensed, the prescription, and the payment to the pharmacy.

58. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program. The data contained in PDEs are data related to payment of claims. The Integrated Data Repository ("IDR") process date is the date when the PDE is transmitted to CMS, such that CMS is informed of the PDE by the Part D Plan Sponsor.

59. In addition, CMS uses the information in the PDE at the end of the payment year to reconcile its advance payments to the sponsor with actual costs the plan sponsor incurred. *See* "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)" (April 27, 2006).

- **CMS Makes Three Types of Payments to Part D Plan Sponsors**

60. Throughout the year, CMS makes prospective payments to Part D Plan Sponsors for three subsidies based on the Sponsors' approved bids: (1) the direct subsidy designed to cover the Sponsor's cost of providing the benefits; (2) the low-income cost-sharing subsidy; and (3) the reinsurance subsidy.

61. The direct subsidy (a monthly capitated payment) is paid to the Part D Plan Sponsor in the form of advance monthly payments equal to the Part D Plan's standardized bid, risk adjusted for health status as provided in 42 C.F.R. § 423.329(b), minus a monthly beneficiary premium as determined in 42 C.F.R. § 423.315(b). In other words, CMS pays a monthly sum to the Part D Plan Sponsor for each Part D beneficiary enrolled in the plan.

62. CMS also makes payments to the Part D Plan Sponsor for premium and cost sharing subsidies on behalf of certain subsidy-eligible individuals as provided in 42 C.F.R. § 423.780 and 42 C.F.R. § 423.782. Cost-sharing subsidies for qualifying low-income individuals are called "Low-Income Cost Sharing Subsidies ("LICS") and are documented and reconciled using PDE data submitted to CMS.

63. Part D sponsors who fail to submit required claims-level information contained in the PDE to CMS risk having to return the monthly payments to CMS during reconciliation. *See* 42 C.F.R. §§ 423.343(b), (c)(2) and (d)(2). In addition, Part D Sponsors are responsible for

correcting submitted PDE data they determine are erroneous. *See* "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)" at 4 (April 27, 2006).

64. After the close of the plan year, CMS is responsible for reconciling the prospective payments to the Part D Sponsor's actual allowable costs by relying upon data elements submitted by Sponsors in their PDE records.

- **Part D Plan Sponsors and Their Contractors Certify Compliance with All Applicable Federal Laws, Regulations and CMS Instructions**

65. In order to receive Part D funds from CMS, Part D Plan Sponsors, their authorized agents, employees, and contractors are required to comply with all applicable federal laws, regulations, as well as CMS instructions.

66. By statute, all contracts between a Part D Plan Sponsor and HHS must include a provision whereby the Plan Sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112.

67. Medicare Part D Plan Sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. § 505(h)(1).

68. CMS regulations require that all subcontracts between Part D Plan Sponsors and downstream entities contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions, including the CSA. 42 C.F.R. § 423.505(i)(4)(iv).

69. A Part D Plan Sponsor is required by federal regulation to certify to the accuracy, completeness and truthfulness of all data related to the payment. This provision, entitled "Certification of data that determine payments," provides in relevant part, as follows:

(1) General Rule. ***As a condition for receiving a monthly payment*** . . . ***the Part D plan***

> ***sponsor agrees that*** its chief executive officer (CEO) chief financial officer (CFO), or ***an individual*** delegated the authority to sign on behalf of one of these officers, . . ***must request payment under the contract on a document that certifies*** (based on best knowledge, information and belief) the ***accuracy, completeness, and truthfulness*** of all data related to payment.
> . . .
> (2) [Part D Sponsor] Certification of Claims Data: The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, . . . must certify (based on best knowledge, information and belief) that the claims data it submits . . . are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.

42 C.F.R. § 423.505(k)(1) & (3) (emphasis added).

70. All approved Part D Plan Sponsors who received payment under Medicare Part D in benefit years relevant to this case submitted the required attestations for data submitted that related to payment. 42 C.F.R. § 423.505(k).

71. The "Certification of data that determines payments" provision of the applicable regulation further provides: "[i]f the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

72. Compliance with the requirement that PDE data submitted by the Plan Sponsor is "true, accurate, and complete," based on best knowledge, information and belief, is a condition of payment to the Plan Sponsor under the Medicare Part D Program. *Id*. Compliance is also material to payment.

73. Medicare only covers drugs that are used for a medically accepted indication, which means a use that is approved under the Food, Drug, and Cosmetic Act, or a use which is supported

by one or more citations included or approved for inclusion in one of the specified compendia. 42 U.S.C. § 1395w-102(e)(1) & (e)(4); 42 U.S.C. § 1396r-8(g)(1)(B)(i) & (k)(6); 42 C.F.R. § 423.100.

74. PDEs submitted to Medicare for drugs that do not have a medically accepted indication do not contain accurate, complete and truthful information about all data related to payment.

75. Medicare only covers drugs that are dispensed upon a prescription. 42 U.S.C. § 1395w-102(e); 42 C.F.R. § 423.100. A "Part D sponsor may only provide benefits for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription." 42 C.F.R. § 423.104(h). A valid prescription must comply "with all applicable State law requirements constituting a valid prescription." 42 C.F.R. § 423.100.

76. Part D plans may also exclude drugs from payment if the drugs are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve functioning of a malformed body part. 42 U.S.C. § 1395w-102(e)(3) (incorporating by reference 42 U.S.C. § 1395y(a)).

77. Prescriptions for controlled substances that are not issued for a legitimate medical purpose, such as for recreational use, are not for "medically accepted indications" and are therefore not covered Medicare Part D drugs. 32 U.S.C. § 1395w(e)(1).

78. Prescriptions for controlled substances that are not issued for a legitimate medical purpose, such as recreational use, are not "valid prescriptions" under Tennessee law and are therefore not covered Medicare Part D drugs. 42 U.S.C. § 423.104(h).

79. PDEs submitted to Medicare for controlled substances that are dispensed when not issued for a legitimate medical purpose by an individual practitioner acting in the usual course of

his or her professional practice do not contain accurate, complete and truthful information about all data related to payment.

TENNESSEE LAW GOVERNING PHARMACIES

80. Tennessee law defines the "Practice of Pharmacy" to mean a "patient-oriented health service profession in which pharmacists interact and consult with patients and other health care professionals to enhance patients' wellness, prevent illness, and optimize outcomes." TENN. CODE ANN. § 63-10-204(39)(A). That same statute further explains that the Practice of Pharmacy involves the "[t]he interpretation, evaluation and implementation of medical orders and prescription orders," and [p]articipation in drug … selection," and "[drug] evaluation, utilization or regimen review." *Id.*

81. The Tennessee Board of Pharmacy's Standards of Practice specifically establish that "A pharmacist shall be responsible for a reasonable review of a patient's record prior to dispensing each medical or prescription order. The review shall include evaluating the … order for: [o]ver-utilization or under-utilization; [t]herapeutic duplication; [d]rug-disease contraindication; [d]rug-drug interactions; [i]ncorrect drug dosage or duration of drug treatment; [and] **clinical abuse/misuse**." TENN. COMP. R. & REGS. § 1140-03-.01(3) (emphasis added).

82. Moreover, under Tennessee law, pharmacists are required to maintain a patient profile or record system which "shall provide for the immediate retrieval of information necessary for the pharmacist to identify previous dispensed medical and prescription orders at the time a medical or prescription order is presented." *Id.* § 1140-03-.01(2). Moreover, with regard to the patient profile, the pharmacy must "make a reasonable effort to obtain, record, and maintain" patient information relevant to pharmacy practice including, "Pharmacist's comments as deemed relevant." *Id.*

83. Consequently, the dispensing of controlled substances when faced with warning signals, without first ensuring that the prescription was issued for a legitimate purpose by a practitioner acting in the usual course of professional practice violates *both* 21 U.S.C. § 842(a) (prohibiting distributing or dispensing in violation of the prescription provisions of 21 U.S.C. § 829) because doing so violated the pharmacist's corresponding responsibility to ensure the legitimacy of the prescription (21 C.F.R. § 1306.04) *and* 21 U.S.C. § 841(a) (prohibiting dispensing except as authorized by the CSA) because the prescription was filled outside of the pharmacist's usual course of professional practice (21 C.F.R. § 1306.06).

84. Tennessee pharmacists have access to Controlled Substance Monitoring Program Board of Pharmacy Patient RX History Reports ("CSMD Reports"). The CSMD reports are compiled by an information system into which pharmacists in Tennessee are required to enter data regarding the controlled substance prescriptions they dispense to patients. This information system allows Tennessee pharmacists to review a patient's controlled substance prescription history before dispensing controlled substances. For example, the pharmacists can determine which doctors have prescribed controlled substances, which pharmacies have dispensed them, the quantities and dosages that have been prescribed and dispensed and when.

TENNESSEE LAW GOVERNING SPECIALLY REGULATED AREAS

85. Prescribing controlled substances in amounts or for durations that are not medically necessary is beyond the scope of professional practice. TENN. COMP. R. & REGS. §§ 0880-02-.14, 1050-02-.13. Prescribing controlled substances for pain will be considered to be for a legitimate medical purpose in certain narrow circumstances, including after a documented medical history, pursuant to a written treatment plan with stated objectives, and considering the risk of medication misuse or diversion. *Id*. §§ 0880-02-.14, 1050-02-.15.

Unlawfulness of a Prescription Is Material to Medicare Payment

86. Compliance with federal and Tennessee state requirements relating to pharmacies' dispensing of controlled substances was and remains material to Medicare's decision to pay the Defendants' claims for reimbursement of controlled substances. Compliance with these requirements is central to the Medicare Part D benefit and is a condition of these medications being covered by Medicare.

87. The government routinely denies payment for controlled substance medications, or seeks to recoup payments already made, when such prescriptions are not issued or dispensed for a legitimate medical purpose in the usual course of professional practice or when the controlled substance medication is intended for purposes of addiction or recreational abuse. For example:

a. The United States Department of Justice ("DOJ") has litigated or settled numerous actions where it was alleged that medical providers and/or pharmacies submitted claims for controlled substance medications to Medicare that lacked a valid prescription, were not for a legitimate medical purpose and lacked a medically accepted indication, or that did not comply with State law. *See, e.g.*, https://www.justice.gov/opa/pr/tennessee-chiropractor-pays-more-145-million-resolve-false-claims-act-allegations (detailing $1.45 million settlement resolving allegations of improper billing for painkillers, including opioids, and including a nurse practitioner's surrender of her DEA registration); *United States ex rel. Norris v. Florence*, Civ. Action No. 2:13-cv-00035 (M.D. Tenn.) (ongoing FCA litigation against a physician for causing the submission of false claims by pharmacies for controlled substances that were not for a legitimate medical purpose); https://www.justice.gov/opa/pr/long-term-care-

pharmacy-pay-315-million-settle-lawsuit-alleging-violations-controlled

(Pharmerica CSA and FCA settlement for improper dispensing of and billing Medicare for unlawfully dispensed prescriptions).

b. The United States has also filed the present action and an accompanying motion for a temporary restraining order and preliminary injunction to halt Defendants' ongoing CSA violations, which if successful would result in stopping further improper Medicare claims for improperly filled controlled substance prescriptions by Defendants.

c. The HHS Secretary's declaration that the opioid epidemic is a national public health emergency under federal law reflects the government's stance to deny payment for improperly dispensed controlled substances.

88. Accordingly, a reasonable person would know that Medicare would not pay for Part D claims submitted to Medicare if it knew that the controlled substance prescriptions at issues were invalid, did not comply with Tennessee state law, and lacked a legitimate medical purpose for a medically accepted indication. Alternatively, these Defendants knew or had reason to know that Medicare would not pay claims submitted to it if these programs knew that the controlled substance prescriptions were invalid as described.

DEFENDANTS' REGULATORY HISTORY

Dale Hollow Pharmacy

89. Dale Hollow was previously registered with DEA as Donaldson Pharmacy with a different registration number. That registration was surrendered in April 2011 after William Donaldson, then the pharmacy's pharmacist-in-charge, was indicted by a federal grand jury on five

counts of illegal distribution of hydrocodone, a Schedule II controlled substance. Donaldson subsequently pleaded guilty and was sentenced to fifteen months imprisonment in 2013.

90. Following the surrender of Donaldson's DEA registration, Donaldson sold his stake in the pharmacy to his sister, Anne Oakley, who was granted a DEA registration for Oakley Pharmacy, Inc. d/b/a Dale Hollow pharmacy on or about April 28, 2011. Following Ms. Oakley's death in 2015, her husband, Charles Oakley, owned the pharmacy in its entirety. Mr. Oakley then sold 51% of the pharmacy to Weir in about April 2014.

91. Polston admitted to DEA investigators that approximately 35% of the prescriptions at Dale Hollow are paid for in cash, and the cash payments are almost exclusively for controlled substances.

92. Polston further admitted that approximately 40% of the prescriptions filled at Dale Hollow are for controlled substances. DEA's review of the pharmacy's own dispensing records shows that on Saturdays, controlled substances account for up to 86% of all prescriptions filled at Dale Hollow.

93. In July 2015, when Polston was already working at Dale Hollow, the Tennessee State Board of Pharmacy ("BOP") placed his license to practice pharmacy on two years' probation for giving early refills and dispensing controlled substances to a family member without a prescription.

94. In January 2016, the BOP suspended Dale Hollow's pharmacy license for a period of five years, with a stay of the suspension for probation after finding that the pharmacy failed to comply with state pharmacy rules designed to protect the health, safety, and welfare of the public. Among the violations noted by the BOP was that the pharmacy failed to properly dispense controlled substances and in a manner consistent with the laws governing the practice of pharmacy.

As of the date of this Complaint, the Tennessee Department of Health indicates that Dale Hollow's state pharmacy license remains "on probation."

95. At approximately 12:48 a.m. on April 19, 2016, the Clay County Sheriff's Office and Celina City Police responded to an alarm call at Dale Hollow. Upon arrival, the officers observed pill bottles laying on the floor near the front door of the pharmacy. When Weir arrived at the property, he refused to allow officers behind the pharmacy counter and ordered them to leave and to not return, stating that he "would rather someone steal everything than [have law enforcement] clear and secure the building."

96. On or about May 6, 2016, the Sheriff of Clay County advised DEA investigators that Donaldson was continuing to work at Dale Hollow Pharmacy notwithstanding his prior criminal conviction for unlawful distribution of controlled substances from that same location.

97. On or about May 12, 2016, DEA investigators conducted an inspection and audit at Dale Hollow. During that inspection, DEA found several record-keeping violations, including the pharmacy's failure to account for several controlled substances. That inspection also caused DEA concern regarding the legitimacy of the pharmacy's dispensing practices, including the pharmacy's apparent filling of prescriptions despite the existence of several indicia of diversion and abuse associated with the prescriptions.

98. As a result of DEA's findings, the agency and Dale Hollow entered into a Memorandum of Agreement in March 2017 that memorialized the deficiencies and DEA's concerns regarding apparent violations of both federal and state law and formally set forth Dale Hollow's commitment to comply with its legal obligations, including with regard to buprenorphine dispensing. The agreement was executed by Weir as "CEO/Owner" of Dale Hollow, as well as by Polston as "Pharmacist-in-Charge."

99. In June 2018, the DEA and the Tennessee BOP re-inspected Dale Hollow and found that seven of 15 controlled substance medications were short on inventory. The top three shortages by volume of drug units were:

- Shortage of 501 oxycodone 30 mg tablets
- Shortage of 477 hydrocodone/acetaminophen 7.5/325 mg tablets
- Shortage of 282 buprenorphine 8 mg tablets

Xpress Pharmacy

100. In 2012, Griffith, the pharmacist-in-charge of Xpress, was disciplined by the Tennessee BOP after stealing hydrocodone while working as a pharmacist at another pharmacy. Griffith completed treatment for alcohol and opioid addiction and his license to practice pharmacy was reinstated after completing a five-year probationary period in 2017.

101. Griffith is not the only pharmacist at Xpress with a derogatory regulatory history. In 1992, Larkin's pharmacist license was suspended for three months, and then placed on probation for five years for unauthorized filling and refilling of prescriptions. In or around December 2003, Larkin tested positive for cocaine, benzodiazepines, and alcohol. After he withdrew from substance abuse treatment against medical advice in 2004, his license to practice pharmacy was revoked. Larkin later acknowledged having been addicted to crack cocaine from late 2003 through 2005. His license was reinstated in 2006 with a five year probation period.

102. On January 26, 2018, Griffith called 911 from Xpress and requested an ambulance for a woman who was passed out in the Xpress bathroom from a possible "overdose." The woman was a 37 year old TennCare beneficiary who was apparently at Xpress to fill a controlled substance prescription dated January 25, 2018. When the police arrived, they administered Narcan, and the woman's condition improved.

103. During an on-site inspection of Xpress in August 2018, DEA determined that approximately 50% of all drugs dispensed at the pharmacy were controlled substances, far in excess of the 15–20% that is typical of retail pharmacies, and twice the level that normally causes alarm to state regulators.

104. DEA further found that 14 of 18 controlled substance medications varied from the listed inventory, including the following:

- Shortage of 300 morphine 60 mg tablets
- Shortage of 638 oxycodone/APAP 7.5/325 mg tablets
- Excess of 1638 buprenorphine 8 mg tablets

105. During the August inspection, Griffith told DEA investigators that Xpress has over $2 million in annual sales, and that approximately 32% of prescriptions are paid for with cash, which are almost exclusively for controlled substances. When asked about his prior consent order, Griffith said that he had been addicted to alcohol and hydrocodone and stolen about 50 hydrocodone tablets from Walgreens. When asked why Xpress is one of the top 20 purchasers of buprenorphine in Tennessee, Griffith replied that a lot of patients in the area are on buprenorphine and that he was working to reduce these amounts.

Defendants' Medicare Fraud Scheme

106. Both Dale Hollow and Xpress participated in the Medicare program at all material times. Upon information and belief, Defendants schemed to obtain substantial, improper reimbursements for controlled substances from the Medicare program.

107. On September 27, 2017, Weir signed a Medicare Electronic Funds Transfer (EFT) form indicating that he sought electronic payments from Medicare for Dale Hollow prescriptions.

Although Weir did not update the EFT form for Xpress, he continued to let the prior form signed by a minority owner remain in effect.

108. From 2012 through 2018, Medicare paid Dale Hollow over $1.4 million for controlled substances, of which over $1 million was for opioids alone. Dale Hollow's Medicare reimbursements included, but were not limited to, the following Schedule II controlled substances:

- Over $193,000 for OxyContin
- Over $144,000 for oxycodone acetaminophen
- Over $100,000 for morphine sulfate ER (extended release)
- Over $60,000 for endocet and
- Over $60,000 for oxycodone HCL

109. From 2012 through 2018, Medicare paid Xpress over $1 million for controlled substances, of which $730,000 was for opioids alone. Xpress's Medicare reimbursements included, but were not limited to, the following Schedule II controlled substances:

- Over $100,000 for oxycodone acetaminophen
- Over $92,000 for OxyContin
- Over $65,000 for endocet
- Over $64,000 for opana ER (extended release) and
- Over $54,000 for fentanyl

110. Dale Hollow actually increased its dispensing of controlled substances to Medicare beneficiaries after it signed the DEA Memorandum of Agreement, such that nearly one in five medications the pharmacy dispensed to Medicare beneficiaries in 2017 was a controlled substance, which is significantly above the national average. Oxycodone-containing products, moreover,

accounted for over 60% of Dale Hollow's Schedule II controlled substance dispensing to Medicare beneficiaries.

111. Dale Hollow's and Xpress' practices in billing Medicare for controlled substances are consistent with "Pill Mill" dispensing, so the pharmacies were in essence "prescription mills" and a "narcotics delivery system."

112. Because scores of controlled substance prescriptions dispensed by Dale Hollow and Xpress did not constitute valid prescriptions that complied with federal and Tennessee state law and were not issued for a legitimate medical purpose or for a medically accepted indication, Medicare would not have paid for the tainted Part D controlled substances medications during the applicable period if Medicare had known that the prescriptions were illegitimate and invalid.

DEFENDANTS' UNLAWFUL CONDUCT

113. From about May 2016 to August 2018, Defendants violated the CSA by dispensing controlled substances in violation of the pharmacist's corresponding responsibility in violation of 21 C.F.R. § 1306.04(a) and outside the usual course of pharmacy practice in violation of 21 C.F.R. § 1306.06.

114. Polston and Griffith, acting in the scope of their employment as pharmacists-in-charge of Dale Hollow and Xpress, and Larkin as a pharmacist at both pharmacies, repeatedly failed to identify or ignored suspicious circumstances and indicia of abuse and diversion, filling controlled substance prescriptions without resolving those indicia, or "red flags," including, but not limited to:

a. Patients presenting with prescriptions for drugs which are known in Tennessee to be drugs of abuse, particularly at high dosage levels;

b. Patients traveling unusual distances to obtain a prescription or fill a prescription;

c. Patients paying high cash (or cash equivalent) prices for prescriptions; and

d. Patients presenting prescriptions for combinations of or multiple drugs which are known to used together by drug abusers as a "cocktail" for their synergistic effect.

e. Patients who are not pregnant, nursing, or have a documented allergy or sensitivity to naloxone presenting a prescription to a Tennessee pharmacy for a formulation of buprenorphine without the abuse-deterrent component.

115. Defendants violated the CSA each time they filled a controlled substance prescription without identifying and resolving those red flags because:

a. They were knowingly filled outside the usual course of professional practice and not for a legitimate medical purpose; therefore they were not pursuant to a valid prescription under 21 U.S.C. § 829 and thereby violated 21 U.S.C. § 842(a)(1).

b. They were knowingly and intentionally dispensed outside the usual course of professional pharmacy practice in violation of 21 C.F.R. 1306.06, and therefore such dispensing and delivering of controlled substances was not authorized by the CSA, and thereby violated 21 U.S.C. § 841(a).

116. Because scores of controlled substance prescriptions dispensed, or caused to be dispensed, by Dale Hollow and Xpress lacked a legitimate medical purpose, were not for a medically accepted indication, and did not constitute valid prescriptions under Tennessee law at

relevant times, Medicare also would not have paid for those Part D medications during the applicable periods.

Specific Examples of Unlawful Dispensing Conduct

117. The examples below illustrate Defendants' unlawful dispensing of controlled substances. Three of the exemplar patients to whom Defendants unlawfully dispensed controlled substances were Medicare beneficiaries. Attached to and made part of this Complaint is Exhibit A,[11] which contains a summary chart of false Medicare claims in this action. The claims identified in Exhibit A are illustrative samples of the types of false claims submitted or caused to be submitted to Medicare by Defendants between May 2016 to August 2018.

118. For example, Dale Hollow, acting through its principals, agents, and employees, including Polston and Larkin, filled controlled substance prescriptions for Patient A – a Medicare beneficiary – for methadone and clonazepam on an approximately monthly basis from January 21, 2017, until as recently as July 11, 2018. Methadone is an opioid and a schedule II controlled substance. Clonazepam is a benzodiazepine and a schedule IV controlled substance. Both drugs have significant respiratory and central nervous system depressant side effects whose respiratory depression risks are significantly heightened when combined together. This is particularly significant in this patient because the patient was also dispensed the non-controlled prescription drug, Spiriva, which is used to treat chronic obstructive pulmonary disease ("COPD").

119. The amount of methadone Patient A has been receiving along with a benzodiazepine was dangerously high – a monthly supply of 500 MMEs daily. The 2016 CDC opioid guideline states: "Clinicians … should avoid increasing dosage to ≥ 90 MME/day or

[11] Exhibit A identifies the beneficiaries by letters and omits the beneficiary names and identification numbers to protect patient privacy. The United States will serve Defendants with a copy of Exhibit A that identifies each patient by name once the pleadings are unsealed.

carefully titrate dosage to ≥ 90 MME/day."[12] Not only did Patient A routinely receive ***more than five times*** the CDC's maximum recommended opioid dosage, but Dale Hollow also dispensed clonazepam at the same time, presenting a clear danger that the CDC's *Guidelines* also address: "Clinicians should avoid prescribing opioid pain medications and benzodiazepines concurrently whenever possible." This is because "[c]oncurrent use is likely to put patients at a greater risk for potentially fatal overdose."[13] One study cited by the CDC found "concurrent benzodiazepine prescription with opioid prescription to be associated with a near quadrupling of risk for overdose death compared with opioid prescription alone."[14] Moreover, the FDA-approved labeling for clonazepam includes a "black box warning" — the most serious type of warning issued by FDA designed to call attention to life-threatening risks— with the bold, all-caps heading: "**WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS**." The warning further states: "Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death."

120. As a result, the combination of methadone and clonazepam prescriptions presented by Patient A, particularly in light of the patient's concurrent treatment for respiratory issues presented serious red flags to Dale Hollow and its pharmacists Polston and Larkin that should have been identified and resolved prior to dispensing.

121. Medicare paid approximately $6,600 for Patient A's methadone and clonazaepam prescriptions detailed above, which as Defendants knew, were not used for a medically accepted indication, lacked a legitimate medical purpose, and failed to comply with Tennessee state law. If

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12 *CDC Guideline*, at 22.

13 *Id.* at 31–32.

14 *Id.* at 32.

Medicare had known that these prescriptions were invalid, it would not have paid for them.

122. In another example, Dale Hollow, acting through its agents, principals, and employees, including pharmacists Larkin and Polston, filled prescriptions for Patient B – who was also a Medicare beneficiary – between January 2017 through at least June 2018 on a monthly basis, while failing to identify, document, or resolve multiple red flags attendant to those prescriptions. Patient B routinely filled prescriptions for multiple controlled substances issued by multiple prescribers reflecting unusual or circuitous travel by Patient B to the prescribers and pharmacy, including traveling 36 miles (nearly an hour drive) from his home to have his prescriptions filled at Dale Hollow.

123. Patient B routinely traveled this extended distance to obtain 120 oxycodone 15 mg tablets and 60 mg morphine sulfate ("M.S.") tablets, with occasional morphine prescriptions for strengths as high as 100 mg. This reflects a daily MME of 290—more than three times the CDC's maximum dosage recommendation of 90 MME.

124. In addition to the unusually high dosage of opioids, Patient B also filled prescriptions for 90 alprazolam 2 mg tablets. Alprazolam (brand name, Xanax) is a schedule IV controlled substance and a known drug of abuse. These prescriptions also represent an unusually high dosage amount, because the 2 mg strength formulation is the highest potency form of alprazolam available. As a benzodiazepine, the FDA-approved label for alprazolam carries the same black box warning as clonazepam to warn of the life-threatening risks of its use with opioids.

125. Notably, Patient B obtained the alprazolam prescriptions from a different prescriber than the one who prescribed the multiple opioids. In order to receive the alprazolam, Patient B traveled nearly 2 hours to a rural area approximately 80 miles south from his home – in the opposite direction from Dale Hollow.

126. The distances traveled, high dosages, and concomitant opioid and benzodiazepine were all serious red flags that should have been resolved prior to dispensing controlled substances to Patient B. Yet, Dale Hollow did not identify, document, or resolve these red flags prior to dispensation.

127. Medicare paid approximately $1800 for Patient B's oxycodone, morphine sulfate, and alprazolam prescriptions detailed above, which as Defendants knew, were not used for a medically accepted indication, lacked a legitimate medical purpose, and failed to comply with Tennessee state law. If Medicare had known that these prescriptions were invalid, it would not have paid for them.

128. In another example, Dale Hollow pharmacists Larkin and Polston filled controlled substance prescriptions for Patient C on an approximately monthly basis from July 1, 2016 until as recently as July 11, 2018. Defendants failed to document identifying or resolving the red flags attendant to the prescriptions presented by Patient C and the significant risks presented by those prescriptions, which included prescriptions for a combination of oxycodone, alprazolam, and carisoprodol. Compounding the suspiciousness, Patient C paid cash for these known drugs of abuse. Those red flags are even more glaring when these prescriptions are presented in combination. Moreover, Patient C had a gap in care in filling prescriptions at Dale Hollow from approximately June 2017 until January 2018, which is itself a red flag. Additionally, when this patient returned from his gap in treatment, he presented a prescription for an increased dosage of oxycodone, which is yet another red flag.

129. Similar red flags were apparent with prescriptions filled at Xpress pharmacy by Griffith and Larkin. For example, Griffith and Larkin filled prescriptions for Patient D, her husband, and her son without resolving the significant risks presented by those prescriptions,

particularly in view of the common household and overlapping drug profile for each of the family members. Griffith and Larkin filled controlled substance prescriptions for Patient D on an approximately monthly basis from November 11, 2016, until as recently as August 15, 2018, for oxycodone, clonazepam, and carisoprodol. Additionally, Patient D received controlled substances from Xpress during this time for phentermine, a schedule IV stimulant. Oxycodone, clonazepam, and carisoporodol is a dangerous combination of controlled substances and well-known in pharmacy practice as a red flag of abuse and diversion. Moreover, although Patient D appeared to have insurance coverage to pay for some prescriptions, she paid cash for the brand name Endocet (oxycodone), which is a red flag in pharmacy practice. Likewise, Patient D's spouse filled brand-name Endocet prescriptions at Xpress on an approximately monthly basis between February 2017 and July 2018 despite the prescriber's indication that a generic was permitted. With only a single exception, Patient D's spouse filled prescriptions exclusively during this period. Moreover, Patient D's son, who lives at the same address, also filled monthly Endocet prescriptions at Xpress between December 2016 and September. Despite these clear red-flags, Griffth and Larkin filled these prescriptions.

130. In one of the most tragic examples of the unlawful dispensing of controlled substances, Xpress pharmacists routinely filled prescriptions for oxycodone and alprazolam for Patient E throughout 2015 and 2016. Both the FDA and the CDC have issued clear warnings about the risks of combining a narcotic and a benzodiazepines, and these risks were well-known in pharmacy practice at the time. Xpress filled only controlled substances for Patient E, with the exception of a single prescription for gabapentin (which is currently a controlled substance under Tennessee, but not federal, law). Although Patient E generally used TennCare, Tennessee's Medicaid program, to pay for oxycodone prescriptions, she paid cash for the alprazolam. On

November 22, 2016, Patient E obtained 90 oxycodone tablets from Xpress. Less than weeks later, Xpress dispensed alprazolam to her. At no time did Xpress resolve these red flags before dispensing. Less than a week later, Patient E was dead at age 46 from what the medical examiner concluded was an overdose of oxycodone and alprazolam – the very drugs she obtained from Xpress.

131. Similarly, Griffith and Larkin ignored various red flags with regard to prescriptions for controlled substances presented by Patient F between March 2016 and February 2017. Those prescriptions included a cocktail of oxycodone and alprazolam – the combination warned against by both CDC and FDA. In addition to this benzodiazepine-opioid combination, Xpress pharmacists dispensed zolpidem tartrate (brand name: Ambien), a hypnotic-sedative that depresses the central nervous system, including respiratory function. On the same day in February 2017, Xpress pharmacists dispensed 180 tablets of oxycodone earlier than the dates specified on the prescriptions to Patient F. The next day, Patient F was dead of "acute combined drug toxicity," including oxycodone.

132. As a final example, Xpress pharmacists Griffith and Larkin filled controlled substance prescriptions for Patient G – a Medicare beneficiary – on an approximately monthly basis from November 2015 through August 2018. Defendants failed to document identifying or resolving the red flags attendant to the prescriptions presented by Patient G and the significant risks presented by those prescriptions, which included prescriptions for a combination of oxycodone, morphine, and alprazolam. These red flags included G's apparent doctor shopping at eight different doctors during this period as well as her overlapping use of two powerful opioids.

133. Medicare paid approximately $8000 for Patient G's oxycodone, morphine, and alprazolam prescriptions detailed above, which as Defendants knew, were not used for a medically

accepted indication, lacked a legitimate medical purpose, and failed to comply with Tennessee state law. If Medicare had known that these prescriptions were invalid, it would not have paid for them.

134. There is reason to believe that these violations of federal law – violations that represent a clear danger to public health and safety – will continue absent an injunction.

135. During DEA's inspection of Dale Hollow in 2018, for example, Weir told DEA that the pharmacies he owned had no obligation to exercise professional judgment or fulfill a corresponding responsibility to ensure that the prescriptions filled were legitimate, stating "Doctors need to be investigated. They are the ones writing prescriptions. We just fill them. **The pharmacist is not responsible."** (emphasis added). Indeed, Weir made this statement in the presence of his subordinate employees. Remarkably, Weir made these statements notwithstanding DEA regulations and the 2016 Memorandum of Agreement that was put in place specifically to address the pharmacy's misconduct, including failing to resolve red flags prior to dispensing.

136. Despite Defendants' knowledge, reckless disregard, or deliberate ignorance of the fact that they were unlawfully dispensing controlled substances, Defendants knowingly made, or caused to be made, and received and retained payments from Medicare for, false and fraudulent claims for controlled substances.

COUNT I – INJUNCTION FOR VIOLATION OF 21 U.S.C. § 842

137. The United States incorporates by reference the allegations contained in paragraphs 1 through 137.

138. Defendants jointly, acting in concert and participation with one another, and through their agents and employees, have repeatedly violated 21 U.S.C. § 842(a)(1), in that they knowingly dispensed controlled substances without a valid prescription issued for a legitimate

medical purpose by a practitioner acting in the usual course of his professional practice pursuant to 21 U.S.C. § 829 and 21 C.F.R. § 1306.04(a).

COUNT II – INJUNCTION FOR VIOLATION OF 21 U.S.C. § 841

139. The United States incorporates by reference the allegations contained in paragraphs 1 through 139.

140. Defendants jointly, acting in concert and participation with one another, and through their agents and employees, have repeatedly violated in 21 U.S.C. § 841(a)(1) in that they repeatedly knowingly and intentionally distributed and dispensed controlled substances while not acting in the usual course of the professional practice of pharmacy, pursuant to 21 C.F.R. § 1306.06.

COUNT III – FALSE OR FRAUDULENT CLAIMS TO MEDICARE IN VIOLATION OF 31 U.S.C. § 3729(a)(1)(A)
(previously 31 U.S.C. § 3729(a)(1) (1986))

141. The United States incorporates by reference the allegations contained in paragraphs 1 through 141.

142. Defendants knowingly, or with reckless disregard, presented, or caused to be presented false or fraudulent claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A), specifically, Defendants submitted, or caused Dale Hollow or Xpress to submit, requests for payment to Part D Plan Sponsors for controlled substance medications that were not dispensed for a legitimate medical purpose under the CSA, and/or that were dispensed without obtaining a valid prescription under Tennessee law, when those claims were not payable as such.

143. Because of Defendants' acts, the United States suffered damages in an amount to be determined at trial, and therefore is entitled to treble damages under the False Claims Act, plus civil penalties of not less than $5,500 to $11,000 per violation for violations that occurred before

November 2, 2015 and of not less than $11,181 and up to $22,363 for violations that occurred after that date.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff United States respectfully requests that this Court declare a judgment in the United States' favor and against Defendants jointly and severally as follows:

1. On Counts 1 and 2 pursuant to 21 U.S.C. § 843(f)(1), 21 U.S.C. § 882, 21 U.S.C. § 842(c), and the Court's own equitable powers:

   a. Declare that Defendants violated the CSA, specifically 21 U.S.C. §§ 829, 841(a)(1 and 842(a)(1);

   b. Enter an order:

      1. Temporarily, preliminarily, and permanently enjoining Defendants and each of their officers, agents, servants, employees, representatives, successors, and assigns, and any and all persons in active concert or participation with them and all persons having or who receive actual notice of these proceedings (collectively "Defendants and their Agents"), from directly or indirectly distributing, dispensing, or possessing with the intent to distribute, or dispense, any controlled substances as defined and identified in 21 U.S.C. §§ 802(6) and 812, and 21 C.F.R. §§ 1308.11 – 1308.15;

      2. Requiring Defendants and their Agents to surrender all controlled substances in their possession, custody, or control to agents or investigators of the DEA immediately on service of the

TRO, and DEA shall maintain any controlled substances surrendered by Defendants pending further order of this Court; and

3. Temporarily, preliminarily and permanently enjoining Defendants and their Agents from altering, deleting, destroying, mutilating, or transferring any record within their possession, custody, or control related to the distribution or dispensation of controlled substances.

c. Enter an order requiring Defendants to pay a civil penalty of $64,820, pursuant to 21 C.F.R. § 85.5, for each individual prescription that was filled in violation of 21 U.S.C. § 842; and

d. Such other relief, including costs, as is just and equitable.

2. On the Third Counts against Defendants, under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

3. All other relief as may be required or authorized by law in the interests of justice.

The United States demands a trial by jury on all issues so triable.

Dated: February 7, 2019

Respectfully Submitted,

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